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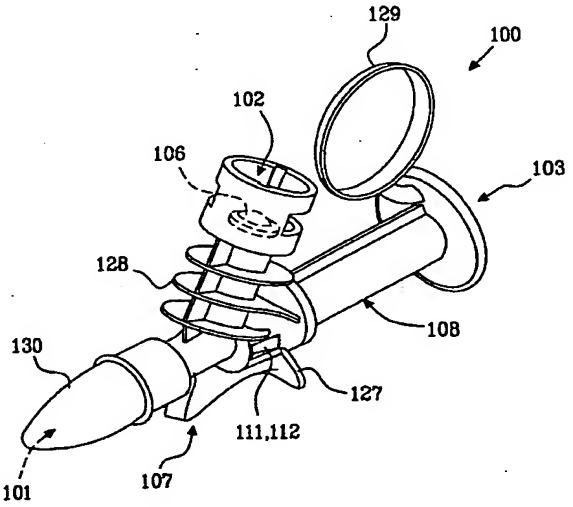
(54) Title: DEVICE FOR MIXING MEDICAL FLUIDS, AND METHOD FOR ENABLING SUCH MIXING



(57) Abstract: A device for mixing medical fluids and method for enabling such mixing. The device (100) exhibits an inlet port (101), an injection port (102), an outlet port (103), a first duct between the injection port (102) and the inlet port (101), and a second duct between the inlet port (101) and the outlet port (103). The injection port (102) is sealed by a fluid-proof membrane (106) which can be penetrated by an injection needle. The device (100) further includes at least a first portion (107) made of a first material and a second portion (108) made of a second, substantially more resilient material, wherein the inlet port (101) and the injection port (102) are included in the first portion (107) and the outlet port (103) is included in the second portion (108), and the first (107) and second (108) portions are attached to each other by means of a combined friction coupling and snap connection.

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Title

Device for mixing medical fluids, and method for enabling such mixing.

Technical field

The present invention relates to a device for mixing medical fluids, wherein the mixing device is of a type exhibiting an inlet port for receiving at least a first medical fluid, an injection port for injection of a second medical fluid, an outlet port for exit of a mixed flow of the first and second medical fluids, a first duct extending between the injection port and the inlet port, and a second duct extending between the inlet port and the outlet port, and where the injection port is sealed by a fluid-proof membrane which can be penetrated by an injection needle when injecting the second medical fluid.

The invention further relates to a method for enabling mixing of medical fluids by means of the device.

Background of the invention

A serious problem in connection with drug preparation, drug administration, and other similar handling is the risk that medical and pharmacological staff are exposed to drugs or solvents which might escape into the ambient air. This problem is particularly serious when the preparation of cytotoxins, antiviral drugs, antibiotics and radiopharmaceuticals are concerned.

For this reason, there has been a need for safer systems for handling and administrating drugs and other medical substances.

Accordingly, U.S. Patent No. 4,564,054 (Gustavsson) discloses a fluid transfer device for transferring a substance from one vessel to another vessel avoiding leakage of liquid and gas contaminants. The disclosed device comprises a first member designed as a hollow sleeve and having a piercing member provided with a passageway. The piercing member is attached to the first member which has a first barrier member at one end just opposite the tip of the piercing member. Thereby, the piercing member can be passed and retracted through the first barrier member which seals one end of the first member. The fluid transfer device further comprises a second member which

is attached to or attachable to one of the vessels or to means arranged to communicate therewith. The second member has a second barrier member, and mating connection means arranged on the first and second members for providing a releasable locking of the members with respect to each other. The barrier members are liquid and gas-proof sealing members which seal tightly after penetration and retraction of the piercing member and prevent leakage of liquid as well as gas contaminants. In the connected position of the first and second members, the barrier members are located in such a way with respect to each other that the piercing member can be passed therethrough. According to US 4,564,054, the above-mentioned piercing member is a needle arranged for puncturing the first and the second barrier members, wherein the end opposite to the one end of the first member has means for sealingly receiving or being permanently attached to an injection syringe or the like for withdrawing and/or adding substance to the vessel attached to the second member. When attached to the first member, the injection syringe or the like communicates with the passageway of the needle, so that in the retracted position the needle is hermetically enclosed in the first member having the injection syringe or the like connected thereto.

Furthermore, the international patent publication No. WO 99/27886 (Fowles et. al) discloses a connector device intended for establishing fluid communication between a first container and a second container. The connector device comprises a first sleeve member having a first and a second end, wherein the first sleeve member has a first attaching member at the first end which is adapted to attach to the first container. The connector device further comprises a second sleeve member which has a first end and a second end. Thereby, the second sleeve member is associated to the first sleeve member and movable with respect thereto from an inactivated position to an activated position, wherein the second sleeve member has a second attaching member at the second end adapted to attach the second sleeve member to the second container. According to WO 99/27886, the connector device further comprises a first and second piercing member projecting from one of the first and second sleeve members for providing a fluid flow path from the first container to the second container, and means for independently hermetically sealing the first and second members.

The administration of medical fluids to a patient can be accomplished by means of inserting a catheter into a patient's vein, and then coupling a source of medical fluid thereto using an administration set including flexible tubing and one or more injection

sites. A typical gravity feeding system for infusion therapy includes a container, e.g. a plastic bag, for the parental solution, a tube extending from the bag and connected to a Y-injection site, and a tube from the Y-injection site to a needle or catheter which is inserted into a vein of the patient.

Typically, the infusion fluid line is connected to the infusion bag by means of a so-called spike device. In this wellknown system, a rigid spike member penetrates a septum sealing a fluid transfer port of the infusion bag in order to establish fluid communication between the infusion bag and the infusion line on which one or several injection sites or ports can be provided. Thereby, the injection of a drug into the infusion fluid normally is accomplished by means of penetrating a septum sealing the injection port using a conventional hypodermic needle. This solution, however, has not been satisfactory from a safety point of view, since it involves a substantial risk of health-hazardous substances escaping into the environment.

For this reason, there has been a need of safer devices for introducing a drug or another medical substance into an infusion fluid of an infusion system.

A number of alternative solutions for introducing a medical substance into an infusion system have been proposed, e.g. those disclosed in U.S. Patents No. 6,245,056 (Walker et al.), 6,113,068 (Ryan), 6,221,065 (Davis), 6,146,362 (Turnbull et al.) and 4,878,897 (Katzin).

Furthermore, the international patent publication WO 98/19724 (Wessman) discloses an improved device for administrating a toxic fluid. The device comprises an infusion device for connection to an infusion bag and is provided with an insertion portion for connecting the bag, and an infusion chamber for dosing a fluid flow via a flow duct in the insertion portion from the bag to an outlet arranged on the chamber. The insertion portion also comprises a ventilating duct which extends between the bag and the outside of the infusion device and ends in a connection arranged on the side of the infusion device for supplying the fluid to be administrated, wherein the connection is provided with at least one membrane which is air tight and penetrable by an injection needle.

Several of the solutions disclosed in the above-mentioned documents enable the introduction of a potentially health-hazardous medical substance into an infusion system to be performed in a safe way. However, the previously proposed solutions

utilise devices which are assembled from a large number of components and which, accordingly, also are expensive to manufacture.

Another drawback of the devices according to prior art is the use of glue or adhesive connections between the different components needed in order to establish a fluid communication between an infusion fluid container and an infusion line connected to a patient. The extensive use of glue or adhesive for these connections is a disadvantage, both since it creates problems with the working environment in the manufacturing plant and also since it increases the manufacturing cost.

Summary of the invention

Accordingly, a first object of the present invention is to provide a device for mixing medical fluids which can be utilised for introducing a potentially health hazardous substance into an infusion system in a safe way, and which device can be manufactured from a small number of individual components at a low cost and if desired without any use of glue or adhesive for connecting the included components.

In accordance with claim 1, this first object is achieved by means of a device exhibiting an inlet port for receiving at least a first medical fluid, an injection port for injection of a second medical fluid, an outlet port for exit of a mixed flow of the first and second medical fluids, a first duct extending between the injection port and the inlet port, and a second duct extending between the inlet port and the outlet port, wherein the injection port is sealed by a fluid-proof membrane which can be penetrated by an injection needle when injecting the second medical fluid. Thereby, the device includes at least a first portion made of a first material and a second portion made of a second material, wherein the second material is substantially more resilient than the first material, and the inlet port and the injection port are included in the first portion and the outlet port is included in the second portion, and the first and second portions are attached to each other by means of a combined friction coupling and snap connection providing a first retention force.

A second object is to provide a method enabling mixing of medical fluids by means of the device according to the invention.

In accordance with claim 23, this second object is achieved by means of a method which includes to provide a mixing device exhibiting an inlet port, an injection port, and an outlet port, and to couple the inlet port to a fluid transfer port of a fluid

container containing a first medical fluid. The method also includes to connect a fluid transfer device having an injection needle to the injection port by means of a double-membrane bayonet coupling, to penetrate fluid-proof membranes included in the double-membrane bayonet coupling by means of the injection needle, to inject a second medical fluid from a second medical fluid-reservoir connected to the fluid transfer device into the first medical fluid, and to pass a mixed flow of the first and second medical fluids through the outlet port into an infusion line. Furthermore, the method includes to provide a combined friction coupling and snap connection in the device between a first portion which is made of a first material and exhibits the inlet port and the injection port, and a second portion which is made of a second material being substantially more resilient than the first material and which exhibits the outlet port.

Further objects of the present invention will become evident from the following description, and the features enabling these further objects to be achieved are listed in the dependent claims.

Brief description of drawings

In the following, the present invention will be described in greater detail with reference to the attached drawings, in which:

Fig. 1 is a schematic perspective view of a device according to a preferred embodiment of the invention;

Fig. 2a is a schematic sectional view through the device in Fig. 1;

Fig. 2b is another schematic sectional view through the device in Fig. 1, showing a combined friction coupling and snap connection according to the invention in greater detail;

Fig. 3 is a partially exploded view of the device in Fig. 2;

Fig. 4 is a schematic illustration of the device of Figs. 1-3 when utilised in an infusion system;

Fig. 5 shows an inlet port of a device according to a first alternative embodiment of the invention;

Fig. 6 is a schematic illustration of a device according to a second alternative embodiment of the invention when utilised in an infusion system; and

Fig. 7 is a schematic sectional view through a device according to a third alternative embodiment of the invention.

Detailed description of preferred embodiments

In the following, a preferred embodiment and a number of alternative embodiments of a device for mixing medical fluids according to the invention will be described in greater detail with reference to the attached Figs. 1 – 7.

The mixing device according to the invention is primarily intended for use when introducing a potentially health-hazardous medical substance in fluid form into an infusion fluid in an infusion system

As illustrated in Figs. 1 – 3, the device 100 exhibits an inlet port 101 for receiving at least a first medical fluid, an injection port 102 for injection of a second medical fluid, and an outlet port 103 for exit of a mixed flow of the first and second medical fluids. Furthermore, as illustrated in Fig. 2a, the device includes a first duct 104 extending between the injection port 102 and the inlet port 101, and a second duct 105 extending between the inlet port 101 and the outlet port 103, wherein the injection port 102 is sealed by a fluid-proof membrane 106 which can be penetrated by an injection needle when injecting the second medical fluid.

According to the invention, as illustrated in Fig. 3, the device 100 further includes at least a first portion 107 made of a first material and a second portion 108 made of a second material, wherein the second material is substantially more resilient than the first material, and the inlet port 101 and the injection port 102 are included in the first portion 107 and the outlet port 103 is included in the second portion 108, wherein the first 107 and second 108 portions are attached to each other by means of a combined friction coupling 109, 110 and snap 111, 112 connection providing a first retention force. This special connection, particularly illustrated in Fig. 2b, enables the device according to the invention to be assembled from a minimum of individual components without any use of glue or adhesive. Furthermore, the less resilient material of the first portion ensures that the inlet and injection ports are shape permanent enough in use, whereas the substantially more resilient material of the

second portion is capable of providing the required sealing action both against the first portion and against additional components which may have to be introduced or into or attached to the outlet port.

In a preferred embodiment of the mixing device 100 according to the invention, as illustrated in Fig. 3, the first portion 107 exhibits an annular, tapering groove 109, and the second portion 108 exhibits an annular, tapering rim 110. Thereby, the first portion 107 exhibits a first snap member 111 and the second portion 108 exhibits a second snap member 112, wherein the groove 109 is designed and arranged for snugly accommodating the rim 110 in order to provide part of the first retention force, and the first snap member 111 is designed and arranged for interacting with the second snap member 112 in order to provide the remainder of the first retention force. However, within the scope of the invention, it is also conceivable with less advantageous embodiments where the combined friction coupling and snap connection is achieved in another way, for example by means of designing the first and second portions with interacting elliptical, square, rectangular or triangular cross-sections, and/or by means of providing several pairs of interacting snap members on said first and second portions.

In the preferred embodiment, as illustrated in Figs. 3 and 4, the outlet port 103 exhibits a tube 113 of the resilient second material, wherein the tube 113 is designed and arranged for snugly accommodating a piercing member 214 of an infusion line 215 in order to retain the piercing member 214 with a second retention force. The piercing member 214 inserted into the outlet port 103 of the mixing device 100 according to the invention can be designed in many different ways, e.g. as a conventional spike member connected to an infusion line.

In the preferred embodiment, as illustrated in Figs. 3 and 4, the outlet port 103 exhibits a tube 113 of the resilient second material, which tube has a first diameter 116 at a first end facing towards the first portion and a second diameter 117 at a second end facing towards the outlet port 103, wherein the tube 113 is designed and arranged with the second diameter 117 being smaller than the first diameter 116 in order to allow leakage-proof insertion of a piercing member 214 of an infusion line 215. It will become evident to the skilled person having read this description that this preferred design ensures that there will be no medical fluid leakage when inserting such a piercing member into the outlet port 103.

As mentioned above, the first portion 107 preferably includes an annular, tapering groove 109, whereas the second portion 108 includes an annular, tapering rim 110, and the outlet port 103 exhibits a tube 113 of the resilient second material, wherein the groove 109 is designed and arranged for retaining the rim 110 with a first retention force and the tube 113 is designed and arranged for retaining a piercing member 214 of an infusion line 215 with a second retention force. In the preferred embodiment, these first and second retention forces both are larger than 15 N in 30 seconds, whereas the first retention force is larger than said second retention force. This feature ensures a sufficient retention force for the normal, intended use of the mixing device according to the invention, and also that the first and second portions cannot be accidentally separated from each other.

In the preferred embodiment, as illustrated in Figs. 2a – 4 together, the outlet port 103 is sealed by a barrier member 118 which is designed and arranged to be ruptured by a piercing member 214 of an infusion line 215 in order to open a passage for the mixed flow from the inlet port 101 to the outlet port 103. In the preferred embodiment, the barrier member 118 is integrated with and made of the same material as the outlet port 103, i.e. the resilient second material. However, within the scope of the invention, it is also conceivable with more expensive and complicated embodiments where the barrier member is made of another material than the outlet port.

In the preferred embodiment, the first portion 107 has been injection-moulded from a thermoplastic polymer material, which preferably is polypropylene, polycarbonate or ABS-polymer.

In the preferred embodiment, the second portion 108 is made of an elastomeric polymer material or a synthetic rubber material.

However, within the scope of the present invention, it is also conceivable with less advantageous embodiments exhibiting another choice of materials, as long as the first and second materials still are able to interact in the combined friction coupling and snap connection and the materials also otherwise are suitable for the purpose.

In one advantageous embodiment, as illustrated in Fig. 4, the inlet port 101 of the device 100 exhibits a rigid spike member 114 for penetrating a fluid-proof septum 119 of a fluid container 120 containing the first medical fluid.

In an alternative embodiment of the invention, illustrated in Figs. 5 and 6 together with Fig. 4, the first portion 307; 407 exhibits a locking member 321; 421 for permanent coupling to a fluid transfer port 122; 222 of a fluid container 120; 220 containing the first medical fluid. In a first alternative design, particularly illustrated in Fig. 5, the inlet port 301 exhibits a rigid spike member 314 having at least one barb member 321 for engaging an internal surface of a fluid transfer port 122 of a fluid container 120 containing the first medical fluid. In a second alternative design, illustrated in Fig. 6, the inlet port 401 exhibits a rigid spike member 414 having at least one hook member 421 for engaging an external surface of a fluid transfer port 222 of a fluid container 220 containing the first medical fluid. Even if not shown in the drawings, the fluid transfer port advantageously can be provided with an interacting locking member, e.g. an edge, recess or protrusion, in order to enhance the desired locking action. The above-described locking members reduce the risk that the mixing device accidentally is detached from the fluid container.

In another advantageous embodiment, as illustrated in Figs. 3 and 4 together, the outlet port 103 of the device 100 is sealed by a barrier member 118 which is designed and arranged to be ruptured by a piercing member 214 of an additional spike member 207 in order to enable passage of the mixed flow from the inlet port 101 via the second duct 105 through the additional spike member 207 into an infusion line 215.

In the preferred embodiment of the invention, as illustrated in Fig. 4, the fluid-proof membrane 106 of the injection port 102 is designed and arranged to be penetrated by the injection needle, wherein the injection needle 123 is provided by a fluid transfer device 124, which can be connected to a second medical fluid-reservoir 125 at one end and which exhibits an additional fluid-proof membrane 126 at the other end which is designed and arranged to be included in a double-membrane 106, 126 bayonet coupling with said injection port 102. Double membrane couplings are described in greater detail in the above-mentioned U.S. Patent No. 4,564,054 (Gustavsson).

In another advantageous embodiment, illustrated in Fig. 1, the device 100 exhibits a base member 127 for allowing the device to rest in a horizontal position before infusion. This embodiment enables an operator to conveniently support the mixing

device on an working surface, for example when attaching the device to an infusion bag.

In still another embodiment, advantageous from an ergonomic point of view and illustrated in Fig. 1, the device 100 exhibits a handle grip 128 for facilitating connection of the device to a fluid container 120. Within the scope of the present invention, it is of course also conceivable with other geometrical designs of such an ergonomic handle grip.

In the preferred embodiment, also illustrated in Fig. 1, the second portion 108 exhibits a cap member 129 for preventing contamination, which cap member can be opened in order to access the outlet port 103.

Advantageously, the mixing device includes less than five components attached to each other. Preferably, as illustrated in Figs. 1 and 2a together, the device is constituted only of the fluid-proof membrane 106, the first portion 107, the second portion 108, and a removable hood 130 for preventing contamination of the inlet port 101. This extraordinarily low number of included components is very cost effective and, furthermore, no glue or adhesive is required when assembling the components.

In another alternative, advantageous embodiment of the invention, illustrated in Fig. 7, the second portion 508 of the device 500 is attached to a drip chamber 531 of an infusion line 515. It should be noted that the second portion 508 in this embodiment has an other geometrical design at the outlet port end 503 than the second portion 108 of the device 100 illustrated in Figs. 1 - 3, but still provides the same combined friction coupling and snap connection to the first portion. This embodiment enables an improved control of the infusion flow to a patient.

In the following, a preferred embodiment and a number of alternative embodiments of a method for enabling mixing of medical fluids by means of a mixing device according to the invention will be described in greater detail with reference to the attached Figs. 1 – 7.

According to the invention, the method includes to provide a mixing device 100 exhibiting an inlet port 101, an injection port 102, and an outlet port 103, and to couple the inlet port 101 to a fluid transfer port 122 of a fluid container 120 containing a first medical fluid. The method also includes to connect a fluid transfer

device 124 having an injection needle 123 to the injection port 102 by means of a double-membrane bayonet coupling, to penetrate fluid-proof membranes 126, 106 included in the double-membrane bayonet coupling by means of the injection needle 123, to inject a second medical fluid from a second medical fluid-reservoir 125 connected to the fluid transfer device 124 into the first medical fluid, and to pass a mixed flow of the first and second medical fluids through the outlet port 103 into an infusion line 215.

According to the invention, the method further includes to provide a combined friction coupling and snap connection in the device 100, between a first portion 107 which is made of a first material and exhibits the inlet port 101 and the injection port 102, and a second portion 108 which is made of a second material being substantially more resilient than the first material and which exhibits the outlet port 103.

In a preferred embodiment, the method further includes to insert an annular, tapering rim 110 of the second portion 108 into an annular, tapering groove 109 of the first portion 107 in order to achieve a snug fit providing a friction coupling between the first 107 and second 108 portions.

In the preferred embodiment, the method further includes to introduce a male snap member 112 into a female snap member 111 in order create the snap connection between the first 107 and second 108 portions.

Advantageously, the method further includes to insert a piercing member 214 of the infusion line 215 into a tube 113 of the second portion 108 in order to achieve a snug fit.

In the preferred embodiment, the method further includes to provide the second portion 108 exhibiting a tube 113 having a first diameter 116 at a first end facing towards the first portion and a second diameter 117 at a second end facing towards the outlet port 103, to select the second diameter 117 to be smaller than the first diameter 116, and to insert a piercing member 214 of the infusion line 215 into the tube 113 from the second end.

In the preferred embodiment, the method further includes to create a first retention force between an annular, tapering groove 109 of the first portion 107 and an annular, tapering rim 110 of the second portion 108, to create a second retention

force between a tube 113 of the second portion 108 and a piercing member 214 of an infusion line, and to select the first and second retention forces to be larger than 15 N in 30 seconds, and the first retention force to be larger than the second retention force.

In the preferred embodiment, the method further includes to rupture a barrier member 118 sealing the outlet port 103 by means of a piercing member 214 of an infusion line 215.

In the preferred embodiment, the method also includes to provide the first portion 107 as an injection-moulded component made of a thermoplastic polymer material, which preferably is polypropylene, polycarbonate or ABS-polymer.

In the preferred embodiment, the method also includes to design the second portion 108 as a component made of an elastomeric polymer material or a synthetic rubber material.

In one advantageous embodiment, the method further includes to design the inlet port 101 as a rigid spike member 114, and to penetrate a fluid-proof septum 119 of a fluid container 120 containing the first medical fluid by means of the spike member 114.

In an alternative embodiment, the method further includes to utilise a locking member 321; 421 provided on the first portion 307; 407 in order to achieve a permanent coupling to a fluid transfer port 122; 222 of a fluid container 120; 220 containing the first medical fluid. Thereby, the method can include to engage an internal surface of the fluid transfer port 122 by means of at least one barb member 321 of a rigid spike member 314 of the inlet port 301 and/or to engage an external surface of the fluid transfer port 222 by means of at least one hook member 421 of a rigid spike member 414 of the inlet port 401.

Particularly advantageously, the method further includes to provide the outlet port 103 with an integrated barrier member 118 made of the same material as the outlet port 103.

In another embodiment, the method further includes to provide the outlet port 103 with a barrier member 118, and to rupture the barrier member 118 by means of a

piercing member in the form of an additional spike member 214 of the infusion line 215.

Advantageously, the method further includes to rest the device 100 in a horizontal position on a base member 127 of the device and/or to handle the device 100 by means of a handle grip 128 when connecting the device to a fluid container 120.

Preferably, the method further includes to open a contamination-preventing cap member 129 of the device 100 in order to access the outlet port 103.

Advantageously, the method includes to assemble less than five components 106, 107, 108, 130 before using the device, and preferably the method includes to assemble the device only from the fluid-proof membrane 106, the first portion 107, the second portion 108, and a removable hood 130 for preventing contamination of the inlet port 101. In the preferred embodiment, the method also includes to remove this contamination-preventing hood 130 from the inlet port 101 before using the device 100.

In an alternative embodiment, the method further includes to provide the second portion 508 having a drip chamber 531 attached thereto.

In the foregoing description, the present invention has been described in connection with a few specific embodiments and with reference to the attached drawings. However, the present invention is by no means strictly confined to these embodiments or to what is shown in the drawings, but the scope of the invention is defined in the following claims.

Claims

1. A device for mixing medical fluids,
said device (100) exhibiting an inlet port (101) for receiving at least a first medical fluid, an injection port (102) for injection of a second medical fluid, an outlet port (103) for exit of a mixed flow of said first and second medical fluids, a first duct (104) extending between said injection port (102) and said inlet port (101), and a second duct (105) extending between said inlet port (101) and said outlet port (103), said injection port (102) being sealed by a fluid-proof membrane (106) which can be penetrated by an injection needle when injecting said second medical fluid,
characterized in that the device (100) includes at least a first portion (107) made of a first material and a second portion (108) made of a second material, wherein said second material is substantially more resilient than said first material, and said inlet port (101) and said injection port (102) are included in said first portion (107) and said outlet port (103) is included in said second portion (108), wherein said first (107) and second (108) portions are attached to each other by means of a combined friction coupling (109, 110) and snap connection (111, 112) providing a first retention force.

2. A device according to claim 1,
characterized in that the first portion (107) exhibits an annular, tapering groove (109), and said second portion (108) exhibits an annular, tapering rim (110), that said first portion (107) exhibits a first snap member (111), and that said second portion (108) exhibits a second snap member (112), wherein said groove (109) is designed and arranged for snugly accommodating said rim (110) in order to provide part of said first retention force, and said first snap member (111) is designed and arranged for interacting with said second snap member (112) in order to provide the remainder of said first retention force.

3. A device according to claim 1,
characterized in that the outlet port (103) exhibits a tube (113) of said resilient second material, wherein said tube (113) is designed and arranged for snugly accommodating a piercing member (214) of an infusion line (215) in order to retain said piercing member (214) with a second retention force.

4. A device according to claim 1,
c h a r a c t e r i z e d i n that that the outlet port (103) exhibits a tube (113) of said resilient second material, said tube having a first diameter (116) at a first end facing towards said first portion and a second diameter (117) at a second end facing towards said outlet port (103), wherein said tube (113) is designed and arranged with said second diameter (117) being smaller than said first diameter (116) in order to allow leakage-proof insertion of a piercing member (214) of an infusion line (215).

5. A device according to claim 1,
c h a r a c t e r i z e d i n that the that the first portion (107) includes an annular, tapering groove (109), that said second portion (108) includes an annular, tapering rim (110), and that said outlet port (103) exhibits a tube (113) of said resilient second material, wherein said groove (109) is designed and arranged for retaining said rim (110) with a first retention force and said tube (113) is designed and arranged for retaining a piercing member (214) of an infusion line (215) with a second retention force in such a way that said first and second retention forces both are larger than 15 N in 30 seconds and said first retention force is larger than said second retention force.

6. A device according to claim 1,
c h a r a c t e r i z e d i n that the outlet port (103) is sealed by a barrier member (118) which is designed and arranged to be ruptured by a piercing member (214) of an infusion line (215) in order to open a passage for said mixed flow from said inlet port (101) to said outlet port (103).

7. A device according to claim 1,
c h a r a c t e r i z e d i n that the first portion (107) has been injection-moulded from a thermoplastic polymer material.

8. A device according to claim 1,
c h a r a c t e r i z e d i n that the first portion (107) is made of polypropylene, polycarbonate or ABS-polymer.

9. A device according to claim 1,
c h a r a c t e r i z e d i n that the second portion (108) is made of an elastomeric polymer material or a synthetic rubber material.

10. A device according to claim 1,
c h a r a c t e r i z e d i n that the inlet port (101) exhibits a rigid spike member (114) for penetrating a fluid-proof septum (119) of a fluid container (120) containing said first medical fluid.

11. A device according to claim 1,
c h a r a c t e r i z e d i n that the first portion (307; 407) exhibits a locking member (321; 421) for permanent coupling to a fluid transfer port (122; 222) of a fluid container (120; 220) containing said first medical fluid.

12. A device according to claim 1,
c h a r a c t e r i z e d i n that the inlet port (301) exhibits a rigid spike member (314) having at least one barb member (321) for engaging an internal surface of a fluid transfer port (122) of a fluid container (120) containing said first medical fluid.

13. A device according to claim 1,
c h a r a c t e r i z e d i n that the inlet port (401) exhibits a rigid spike member (414) having at least one hook member (421) for engaging an external surface of a fluid transfer port (222) of a fluid container (220) containing said first medical fluid.

14. A device according to claim 1,
c h a r a c t e r i z e d i n that the outlet port (103) is sealed by a barrier member (118) which is integrated with and made of the same material as said outlet port (103).

15. A device according to claim 1,
c h a r a c t e r i z e d i n that the outlet port (103) is sealed by a barrier member (118) which is designed and arranged to be ruptured by a piercing member (214) of an additional spike member (207) in order to enable passage of said mixed flow from said inlet port (101) via said second duct (105) through said additional spike member (207) into an infusion line (215).

16. A device according to claim 1,
characterized in that the fluid-proof membrane (106) of said injection port (102) is designed and arranged to be penetrated by said injection needle, wherein said injection needle (123) is provided by a fluid transfer device (124), which can be connected to a second medical fluid-reservoir (125) at one end and which exhibits an additional fluid-proof membrane (126) at the other end which is designed and arranged to be included in a double-membrane (106, 126) bayonet coupling with said injection port (102).

17. A device according to claim 1,
characterized in that the device (100) exhibits a base member (127) for allowing the device to rest in a horizontal position before infusion.

18. A device according to claim 1,
characterized in that the device (100) exhibits a handle grip (128) for facilitating connection of said device to a fluid container (120).

19. A device according to claim 1,
characterized in that the second portion (108) exhibits a cap member (129) for preventing contamination which can be opened in order to access said outlet port (103).

20. A device according to claim 1,
characterized in that the device includes less than five components attached to each other.

21. A device according to claim 1,
characterized in that the device is constituted only of said fluid-proof membrane (106), said first portion (107), said second portion (108), and a removable hood (130) for preventing contamination of said inlet port (101).

22. A device according to claim 1,
characterized in that the second portion (508) of said device (500) is attached to a drip chamber (531) of an infusion line (515).

23. A method for enabling mixing of medical fluids,
said method including:
- to provide a mixing device (100) exhibiting an inlet port (101), an injection port (102), and an outlet port (103);
- to couple said inlet port (101) to a fluid transfer port (122) of a fluid container (120) containing a first medical fluid;
- to connect a fluid transfer device (124) having an injection needle (123) to said injection port (102) by means of a double-membrane bayonet coupling;
- to penetrate fluid-proof membranes (126, 106) included in said double-membrane bayonet coupling by means of said injection needle (123);
- to inject a second medical fluid from a second medical fluid-reservoir (125) connected to said fluid transfer device (124) into said first medical fluid; and
- to pass a mixed flow of said first and second medical fluids through said outlet port (103) into an infusion line (215),
c h a r a c t e r i z e d i n that the method further includes to provide a combined friction coupling and snap connection in said device (100) between a first portion (107) which is made of a first material and exhibits said inlet port (101) and said injection port (102), and a second portion (108) which is made of a second material being substantially more resilient than said first material and which exhibits said outlet port (103).

24. A method according to claim 23,
c h a r a c t e r i z e d i n that the method further includes to insert an annular, tapering rim (110) of said second portion (108) into an annular, tapering groove (109) of said first portion (107) in order to achieve a snug fit providing a friction coupling between said first (107) and second (108) portions.

25. A method according to claim 23,
c h a r a c t e r i z e d i n that the method further includes to introduce a male snap member (112) into a female snap member (111) in order create a snap connection between said first (107) and second (108) portions.

26. A method according to claim 23,
c h a r a c t e r i z e d i n the method further includes to insert a piercing member (214) of said infusion line (215) into a tube (113) of said second portion (108) in order to achieve a snug fit.

27. A method according to claim 23,
c h a r a c t e r i z e d i n the method further includes to provide said second portion (108) exhibiting a tube (113) having a first diameter (116) at a first end facing towards said first portion and a second diameter (117) at a second end facing towards said outlet port (103), to select said second diameter (117) to be smaller than said first diameter (116), and to insert a piercing member (214) of said infusion line (215) into said tube (113) from said second end.

28. A method according to claim 23,
c h a r a c t e r i z e d i n that the method further includes to create a first retention force between an annular, tapering groove (109) of said first portion (107) and an annular, tapering rim (110) of said second portion (108), to create a second retention force between a tube (113) of said second portion (108) and a piercing member (214) of an infusion line, and to select said first and second retention forces to be larger than 15 N in 30 seconds and said first retention force to be larger than said second retention force.

29. A method according to claim 23,
c h a r a c t e r i z e d i n that the method further includes to rupture a barrier member (118) sealing said outlet port (103) by means of a piercing member (214) of an infusion line (215).

30. A method according to claim 23,
c h a r a c t e r i z e d i n that the method further includes to provide the first portion (107) as an injection-moulded component made of a thermoplastic polymer material.

31. A method according to claim 23,
c h a r a c t e r i z e d i n that method further includes to provide the first portion (107) as a component made of polypropylene, polycarbonate or ABS-polymer.

32. A method according to claim 23,
c h a r a c t e r i z e d i n that the method further includes to design the second portion (108) as a component made of an elastomeric polymer material or a synthetic rubber material.

33. A method according to claim 23,
characterized in that the method further includes to design the inlet port (101) as a rigid spike member (114), and to penetrate a fluid-proof septum (119) of a fluid container (120) containing said first medical fluid by means of said spike member (114).

34. A method according to claim 23,
characterized in that the method further includes to utilise a locking member (321; 421) provided on said first portion (307; 407) in order to achieve a permanent coupling to a fluid transfer port (122; 222) of a fluid container (120; 220) containing said first medical fluid.

35. A method according to claim 23,
characterized in that the method further includes to engage an internal surface of a fluid transfer port (122) of a fluid container (120) containing said first medical fluid by means of at least one barb member (321) of a rigid spike member (314) of said inlet port (301).

36. A method according to claim 23,
characterized in that the method further includes to engage an external surface of a fluid transfer port (222) of a fluid container (220) containing said first medical fluid by means of at least one hook member (421) of a rigid spike member (414) of said inlet port (401).

37. A method according to claim 23,
characterized in that the method further includes to provide the outlet port (103) with an integrated barrier member (118) made of the same material as said outlet port (103).

38. A method according to claim 23,
characterized in that the method further includes to provide the outlet port (103) with a barrier member (118), and to rupture said barrier member (118) by means of a piercing member (214) in form of an additional spike member (207) of said infusion line (215).

39. A method according to claim 23,
characterized in that the method further includes to rest the device (100) in a horizontal position on a base member (127) of said device.

40. A method according to claim 23,
characterized in that the method further includes to handle said device (100) by means of a handle grip (128) when connecting said device to a fluid container (120).

41. A method according to claim 23,
characterized in that the method further includes to open a contamination-preventing cap member (129) of said device (100) in order to access said outlet port (103).

42. A method according to claim 23,
characterized in that the method includes to assemble less than five components (106, 107, 108, 130) before using said device.

43. A method according to claim 23,
characterized in that the method includes to assemble the device only from said fluid-proof membrane (106), said first portion (107), said second portion (108), and a removable hood (130) for preventing contamination of said inlet port (101).

44. A method according to claim 23,
characterized in that the method further includes to remove a contamination-preventing hood (130) from said inlet port (101) before using said device (100).

45. A method according to claim 23,
characterized in that the method further includes to provide said second portion (508) having a drip chamber (531) attached thereto.

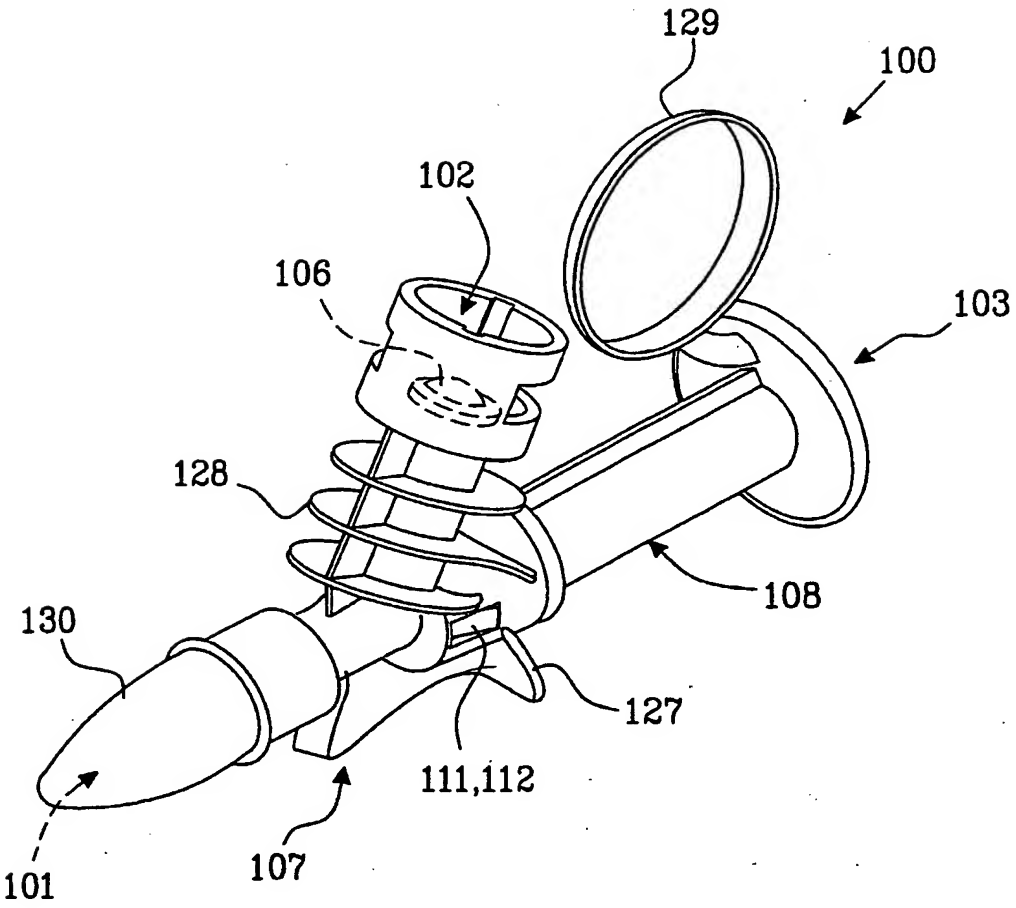

FIG. 1

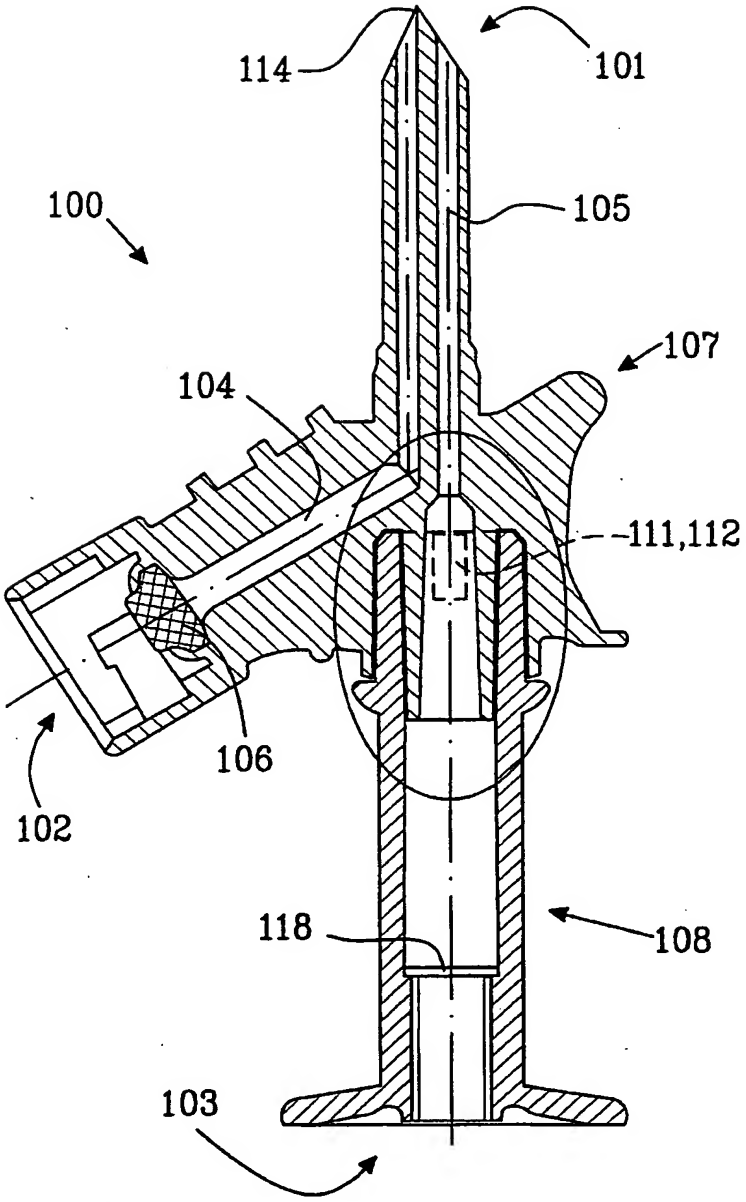
114
101
100
105
107
104
111,112
106
102
118
108
103

FIG.2a

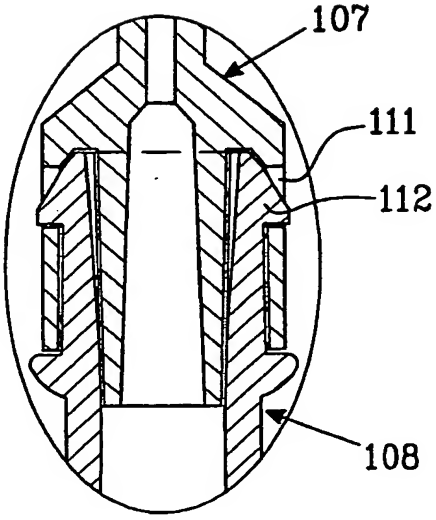
107
111
112
108

FIG.2b

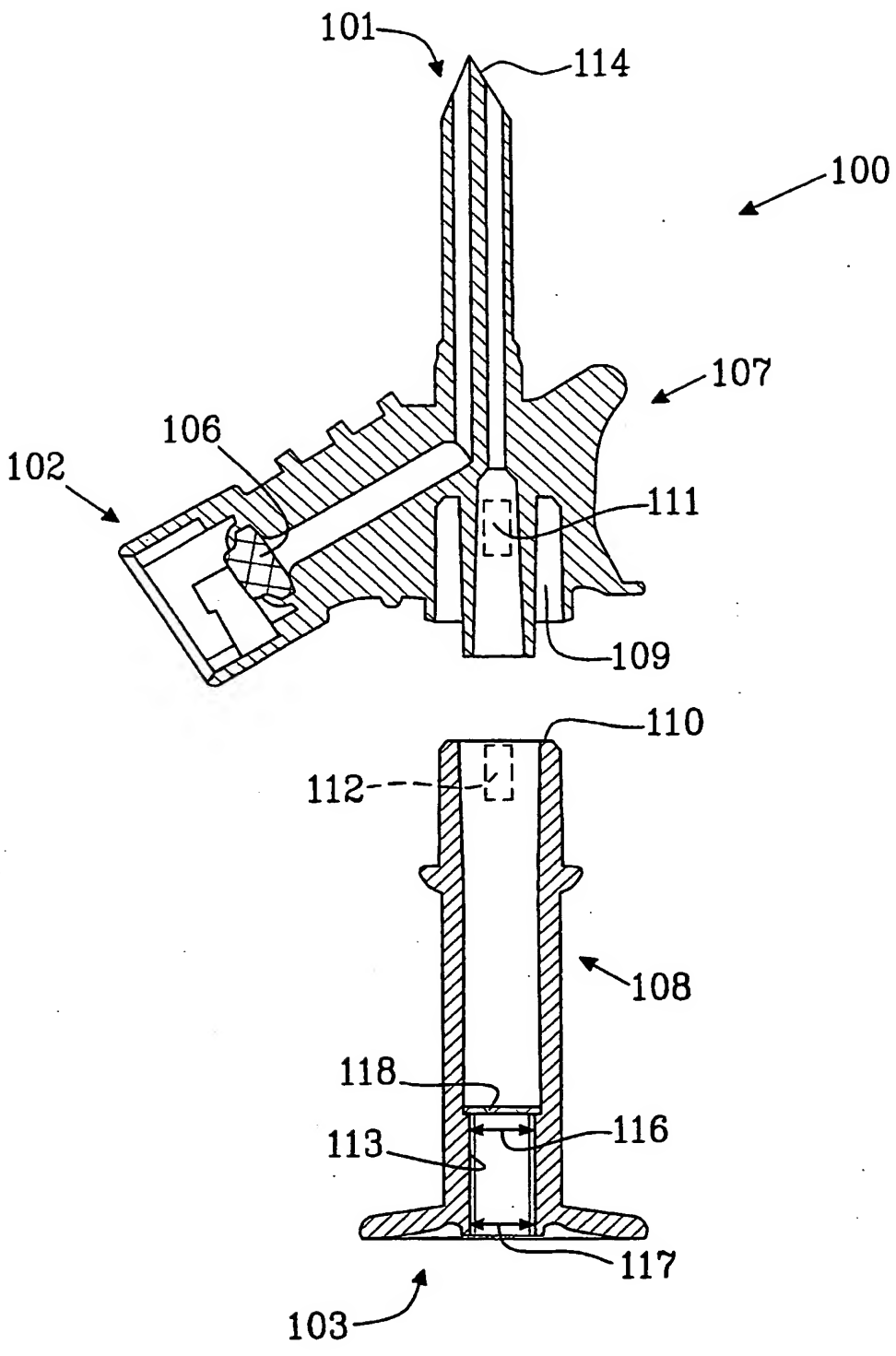

FIG.3

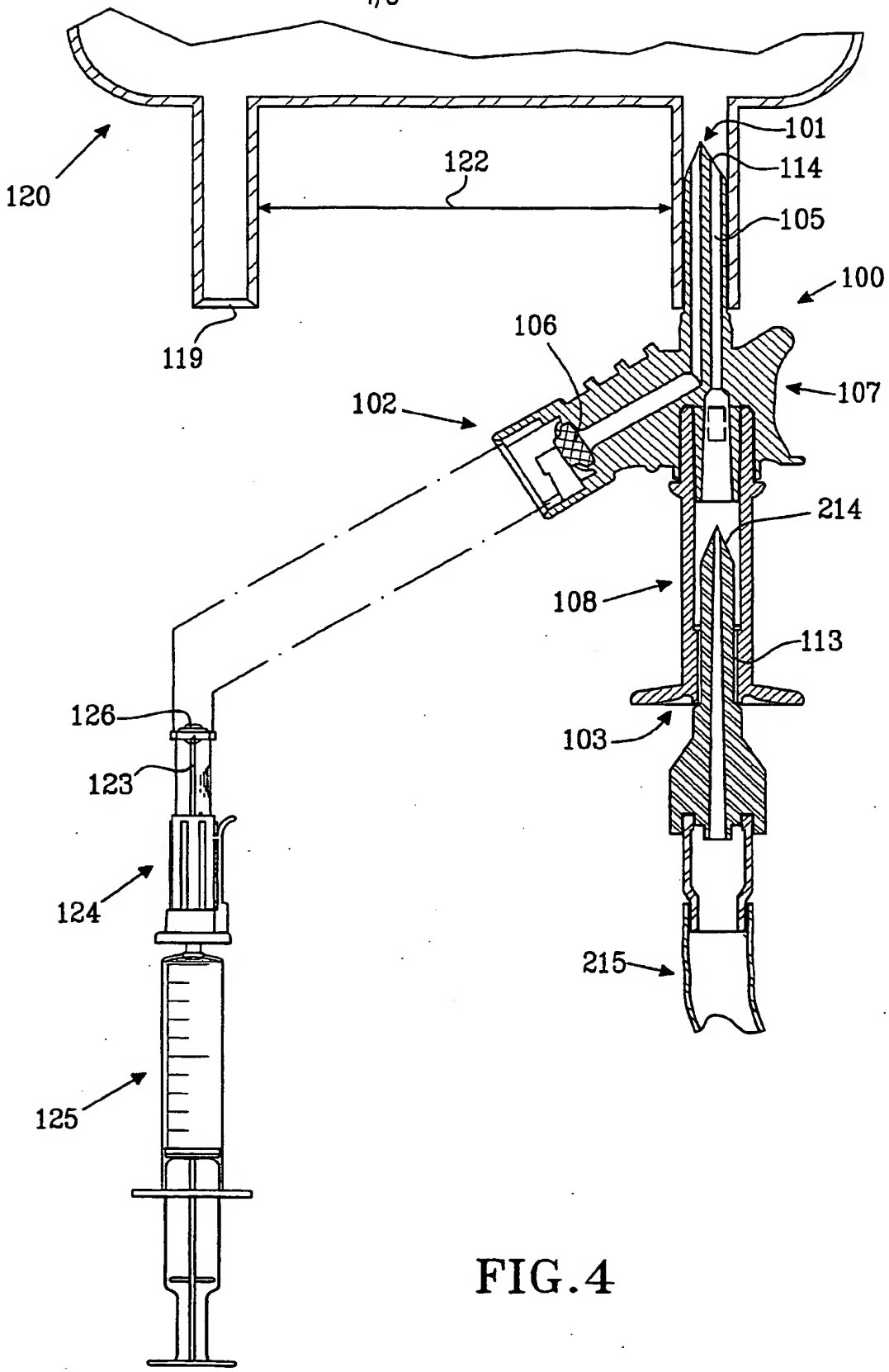
120
122
101
114
105
100
119
106
107
102
214
108
113
126
103
123
124
215
125

FIG.4

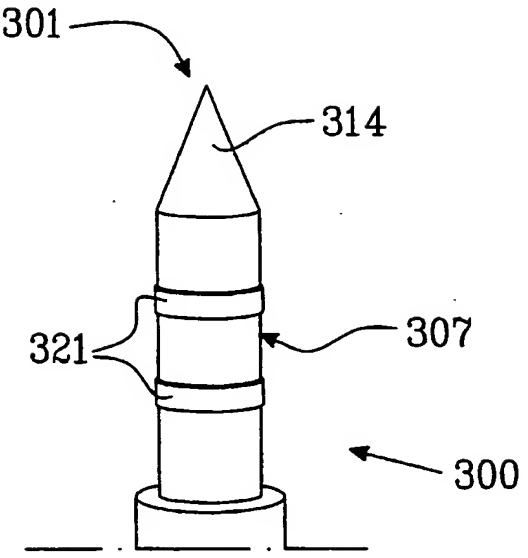

FIG.5

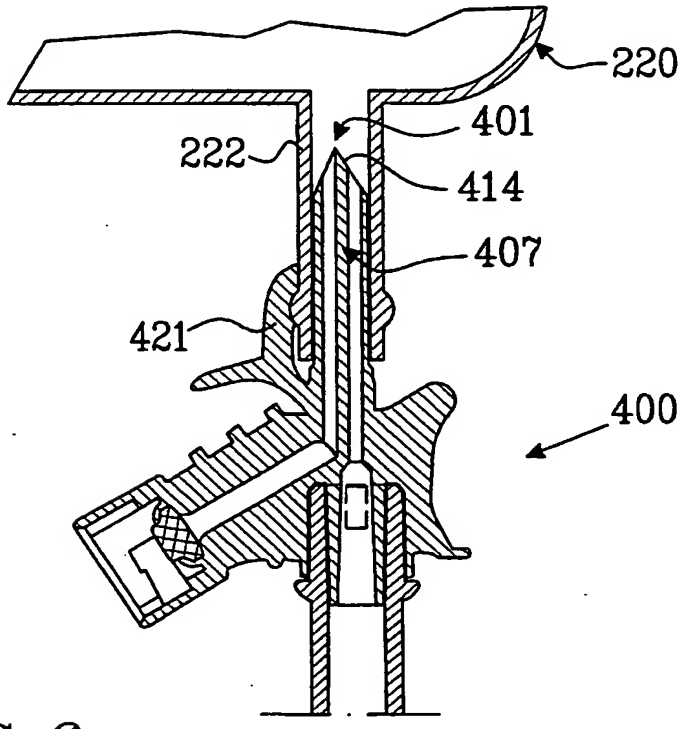

FIG.6

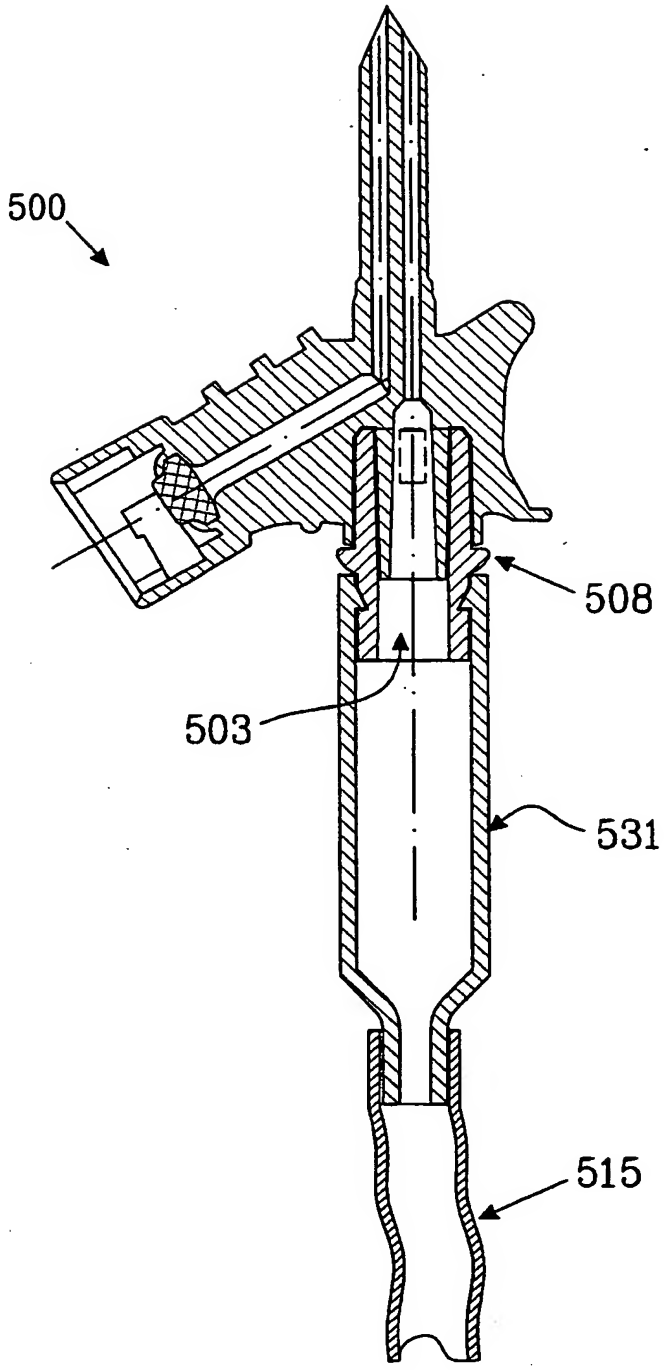

FIG.7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 03/00559

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61M 39/18, A61M 5/14
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-INTERNAL, WPI DATA, MEDLINE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0884059 A2 (FILTERTEK B.V.), 16 December 1998 (16.12.98), figure 1, abstract ---	1-45
A	EP 0677300 A1 (PIERREL OSPEDALI S.P.A), 18 October 1995 (18.10.95), figure 1, abstract ---	1-45
A	EP 1066812 A2 (FRESENIUS KABI DEUTSCHLAND GMBH), 10 January 2001 (10.01.01), figure 1, abstract ---	1-45

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 June 2003	30 -06- 2003
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Patrik Blidefalk/mj Telephone No. +46 8 782 25 00

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 03/00559

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DATABASE WPI Week 199916 Derwent Publications Ltd., London, GB; Class B07, AN 1999-184143 & JP 11 033124 A ((SHES)NIPPON SHERWOOD KK), 9 February 1999 (09.02.1999) -- --------	1-45

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 03/00559

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		DE 19720054 A,C	19/11/98
		ES 2125212 T	01/03/99
		US 6290682 B	18/09/01
EP 0677300 A1	18/10/95	IT 237675 Y	26/09/00
		IT 1274666 B	24/07/97
		IT MI940680 D,U,V	12/04/96
EP 1066812 A2	10/01/01	AT 233531 T	15/03/03
		DE 19930791 A	11/01/01
		DE 50001361 D	00/00/00